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Jeanne Lupton

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Nicholas M. Valiante, Jr.

For: *Use of Tryptanthrin Compounds for Immune Potentiation*

Serial No.: 10/762,873

Filed: 01/21/04

Examiner: Young Soo Chong

Art Unit: 1617

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is in response to the Office Action mailed on July 13, 2005. The shortened one-month period for response to the Office Action expires on August 13, 2005. Accordingly, Applicants believe that this response is timely filed.

Applicants do not believe that any fee(s) is due for this filing. However, should any fee(s) be due, the Commissioner is hereby authorized, under 37 C.F.R. §§ 1.16-1.17, to charge any fee that may be due to Deposit Account No. 03-1664. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 03-1664.

In the Office Action, a restriction requirement was imposed under 35 U.S.C. 121 between the claims of Groups I-XIII. This restriction is respectfully traversed.

The restricted Groups of present Office Action have recognized: tryptanthrins of formula I (optionally in a kit) or II that can be used in conjunction with antigen(s) for enhancing the immune response and/or treating cancer. Somehow, a 13-way restriction has been formulated therefrom, by which examination of each group would presumably render the search/examination of another group burdensome.

Specifically, a restriction was made between Group I, II, III, and IV, which are drawn to methods of enhancing an immune response with an antigen derived from bacterial pathogens, parasitic pathogens, viral pathogens, and fungal pathogens, respectively. Groups V-VIII were analogously restricted. No rationale was given for the restriction between antigens. "The applicant is given, by the statute, the right to claim his invention with limitations he regards as necessary to circumscribe that invention... If however a claim is to be divided up and presented into several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be equivalent of the original claim." *In re Weber* 198 USPQ 328 at 331. If Applicants were to pursue the four antigens in claim 2 in separate applications, as suggested by the restriction requirement of Groups I-VIII, the resulting claims, 20,000+ dollars later, would still not be restored to an equivalent of claim 1. The Examiner has effectively rejected claim 1 in its totality, without a review on its merits, and required that Applicants pursue a fragmented version of claim 2 instead, which is clearly an improper restriction requirement. Even greater evidence toward the improper and unnecessary nature of the restriction between Groups I-VIII is that they are classified in the same class/subclass. Furthermore, the searches required on these four antigens in conjunction with a tryptanthrin would not only not be burdensome, but likely identical. The Examiner's attention is further drawn to issued US Patent No. 6,207,646 wherein claim 1 is drawn to a particular nucleotide in conjunction with an antigen and subsequently claim 11 specifies that "the antigen is selected from the group consisting of proteins, polysaccharides, polysaccharide conjugates, glycolipids, viruses, bacteria, fungi, parasites, and allergens."

Formula I in Groups I-IV, IX, XII and Formula II in Groups V-VIII, X, XI were improperly restricted as well. Although Formula I and Formula II vary in scope, they do not render a restriction requirement proper, otherwise any dependent claim could be restricted from its parent. Although convenient because of different identifiers (i.e. I and II) the search for each is not burdensome and essentially the same. The restriction between Formula I and II is unnecessary and respectfully traversed.

The Examiner identified a difference between the type of claims (i.e. product vs. process of use) in Groups IX, X and I-VIII, X and determined that a restriction was proper because "the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product." Consequently, it was presumably determined *post hoc* that the search required for Examination of the groups would be burdensome: "[b]ecause these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper."

According to §803 of the MPEP, "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." The search required for Group I-XIII, will not be burdensome, and turn up the same references; the reason being, in all searches the common denominator is the composition comprising a tryptanthrin. Concomitant searches of the groups would be redundant and inefficient.

Additionally, according to §803.02 of the MPEP "Since decisions in *In re Weber* and *In re Haas*, it is improper to refuse that which applicants regard as their invention unless the subject matter lacks unity of invention. *In re Harnish* 631 F.2d 716. Broadly, unity of invention exists where the compounds included within a Markush group (1) share common utility and (2) share a substantial structural features disclosed as being essential to that utility." Likewise, all present claims share the tryptanthrin moiety and involve a common utility, namely immunotherapy. The purported fragmentation of Applicants claims would provide little-to-no reduction in the search/examination process, while completely altering that which Applicants chose to claim as their invention.

Applicants fully acknowledge the time constraints on the Examiner, but respectfully contend that the search criteria for Groups I-XIII will be similar enough so as not to seriously burden the Examiner. Applicants request that the restriction requirement imposed be reconsidered and withdrawn. Furthermore, should the restriction be maintained in part, it is respectfully requested that the aforementioned material improperly excluded from Groups I-XII be made available for election. Nonetheless, as required, Applicants provisionally elect the claims of Group IX (claims 12-17 and 19) for examination with traverse. Applicants provisionally elect the species 8-nitroindolo[2,1-b]quinazoline-6,12-dione (Compound No 1001). The claims of Group IX that read on the elected species include claims 12-17 and 19.

The Examiner is cordially invited to telephone Joel Silver at (510) 923-7319 if the Examiner believes such would be helpful in advancing the application to issuance.

Respectfully Submitted,

Date July 22, 2005

By _____

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